

AD _____

GRANT NUMBER DAMD17-95-1-5033

TITLE: Assessment of Embedded Sensors for Health-Status
Monitoring

PRINCIPAL INVESTIGATOR: Daniel L. Schodek

CONTRACTING ORGANIZATION: Harvard University
Cambridge, Massachusetts 02138

REPORT DATE: July 1996

TYPE OF REPORT: Final

PREPARED FOR: Commander
U.S. Army Medical Research and Materiel Command
Fort Detrick, Frederick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for public release;
distribution unlimited

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

DTIC QUALITY INSPECTED 2

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Washington Headquarters Services, Directorate for Information Operations and Reports, 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302, and to the Office of Management and Budget, Paperwork Reduction Project (0704-0188), Washington, DC 20503.

1. AGENCY USE ONLY (Leave blank)		2. REPORT DATE July 1996	3. REPORT TYPE AND DATES COVERED Final (14 May 95 - 30 Jun 96)	
4. TITLE AND SUBTITLE Assessment of Embedded Sensors for Health-Status Monitoring			5. FUNDING NUMBERS DAMD17-95-1-5033	
6. AUTHOR(S) Daniel L. Schodek				
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Harvard University Cambridge, Massachusetts 02138			8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materiel Command Fort Detrick Frederick, Maryland 21702-5012			10. SPONSORING/MONITORING AGENCY REPORT NUMBER	
11. SUPPLEMENTARY NOTES			19961113 112	
12a. DISTRIBUTION / AVAILABILITY STATEMENT Approved for public release; distribution unlimited			12b. DISTRIBUTION CODE	
13. ABSTRACT (Maximum 200) newly developing advanced medical technologies based on remote diagnosis, consultation and treatment offer the potential for improving outcomes by extending advanced health care more directly into the environments that military patient-users actually inhabit or work within; such as military housing, workplace or task environments, outpatient clinics, and deployable health care modules. This approach promises to improve access and reduce costs by reducing demands to use specialized medical facilities for common care needs. This project has assessed the feasibility of embedding different kinds of sensors for monitoring patient-user vital signs and other health measures directly into common architectural components and linking these sensors to a telemedicine system. Following workshops to develop user needs statements, a concept design for a health-sensing habitation environment was developed, and specific components were explored. A preliminary prototype of a 'health care chair' was developed. The project demonstrated the feasibility of the general approach.				
14. SUBJECT TERMS Health monitoring, sensors, remote diagnosis, medical facilities			15. NUMBER OF PAGES 24	
			16. PRICE CODE	
17. SECURITY CLASSIFICATION OF REPORT Unclassified	18. SECURITY CLASSIFICATION OF THIS PAGE Unclassified	19. SECURITY CLASSIFICATION OF ABSTRACT Unclassified	20. LIMITATION OF ABSTRACT Unlimited	

FOREWORD

Opinions, interpretations, conclusions and recommendations are those of the author and are not necessarily endorsed by the U.S. Army.

____ Where copyrighted material is quoted, permission has been obtained to use such material.

____ Where material from documents designated for limited distribution is quoted, permission has been obtained to use the material.

____ Citations of commercial organizations and trade names in this report do not constitute an official Department of Army endorsement or approval of the products or services of these organizations.

____ In conducting research using animals, the investigator(s) adhered to the "Guide for the Care and Use of Laboratory Animals," prepared by the Committee on Care and use of Laboratory Animals of the Institute of Laboratory Resources, National Research Council (NIH Publication No. 86-23, Revised 1985).

____ For the protection of human subjects, the investigator(s) adhered to policies of applicable Federal Law 45 CFR 46.

____ In conducting research utilizing recombinant DNA technology, the investigator(s) adhered to current guidelines promulgated by the National Institutes of Health.

____ In the conduct of research utilizing recombinant DNA, the investigator(s) adhered to the NIH Guidelines for Research Involving Recombinant DNA Molecules.

____ In the conduct of research involving hazardous organisms, the investigator(s) adhered to the CDC-NIH Guide for Biosafety in Microbiological and Biomedical Laboratories.


Principal Investigator's Signature


Date

FINAL SUMMARY PROJECT REPORT

DAMD 17-95-1-5033

Daniel L. Schodek
Graduate School of Design
Harvard University
Cambridge, MA 02138

SUPPORTING PROJECT REPORTS (AVAILABLE ON REQUEST):

- Addington, D. Michelle, *"Survey of Biosensors"*
Report 95:9-1B: Advanced Health-care Environments, GSD, Harvard University,
Cambridge, MA., 1995.
- Addington, D. Michelle, *"Non-Invasive Monitoring: Urinalysis"*
Report 95:12-1A: Advanced Health-care Environments,
GSD, Harvard University, Cambridge, MA., 1995.
- Dorland, John L., *"Focus Groups on Provider Requirements for Health-Sensing
Environments: Group #1: Physicians"*
Wellington Technology Integration, Kingston, Ontario, 1996.
(Included as Report 96:6-1A, GSD, Harvard)
- Dorland, John L., *"Focus Groups on Provider Requirements for Health-Sensing
Environments: Group #1: Home Care Service Providers"*
Wellington Technology Integration, Kingston, Ontario, 1996.
(Included as Report 96:6-1B, GSD, Harvard)
- Schodek, Daniel, *"The Health-Care Chair,"*
Report 96:6-1A: Advanced Health-care Environments,
GSD, Harvard University, Cambridge, MA., 1996.

OTHER RELATED REPORTS:

- Schodek, D., Kaplan, K., Rodriguez, P., *"Patient Transfer Pad,"*
Report 95:6-1B-R: Advanced Health-care Environments,
Harvard, Cambridge, MA. 1995.
- Schodek, D., Kaplan, K., Rodriguez, P., *"Deployable Health-care Modules:
New Directions,"*
Report 95:6-1B-R: Advanced Health-care Environments,
Harvard University, Cambridge, MA., 1995.

EMBEDDED SENSORS FOR HEALTH-STATUS MONITORING

OVERALL PROJECT OBJECTIVES

Newly developing advanced medical technologies based on remote diagnosis, consultation and treatment offer the potential for improving outcomes by extending advanced health-care more directly into the environments that the end patient-user actually inhabits. Many of these technologies can potentially be incorporated into common architectural settings and components with the intent of creating "*health-sensing environments*". Target settings include common living environments (military housing), task environments (workplaces, educational facilities), outpatient clinics (non specialized medical facilities), deployable health-care modules and other forms of non-traditional medical facilities. These health-sensing habitation and task environments can be in either military or civilian settings.

Current telemedicine systems seeking to serve habitation and task environments focus primarily on remote visualization and communication. More than remote consultation, however, is possible. The workplace or habitation environment can ultimately be envisioned as an active health-status monitoring and care facility. Devices exist or can be developed which would allow common health measures to be non-invasively obtained, recorded, and, if appropriate, reported to a health care provider for expert analysis and treatment response. Similar opportunities exist for many different disease-specific and/or post-operative monitoring and care needs.

In terms of military health-care delivery objectives, the applicability of an approach focusing on providing care in common environments relates to the spectrum of health-care needs ranging from post-operative situations following more immediate far forward casualty care all the way through to the diverse and extensive set of needs associated with the peacetime military (see Figure 1). While the importance of technologies for far forward casualty care cannot be overstated, it must also be recognized that a significant portion of health-care delivery needs in the military lie elsewhere. There are a variety of different approaches suitable for this broader approach to military health-care delivery.

As noted in Figure 2, the activities undertaken in this specific research project broadly lie within the critical area of integrating the many new medical device technologies currently under development at DARPA and

elsewhere (including, for example, telesurgery) into the environments and settings in which care actually occurs.

A specific project intent has been to study ways that health-care objectives can be met in common architectural settings rather than only in highly specialized medical facilities. In addition to the many benefits normally discussed for military telemedicine systems, it is believed that providing health-care in common habitation or task environment settings will ultimately lead to reduced costs by allowing less reliance to be placed on the use of specialized (and invariably costly) medical environments for many common care situations. It is also believed that health-care quality can also be ultimately improved by providing longer term monitoring, compliance, and treatment possibilities than are normally possible in today's medical settings. A closely associated goal is that of providing a way for individuals to more easily assume greater responsibility for their own health-care needs, which, in turn, can potentially lead to additional cost reductions (via healthier military personnel) and quality improvements.

THE DEFENSE HEALTHCARE ENVIRONMENT

FORWARD COMBAT
CASUALTY CARE

THE PEACE-TIME
MILITARY



**FIELD MEDICS
AMBULANCES
HELICOPTERS**

- Triage
- Life Support

**DEPLOYABLE
HOSPITALS**

- Life Support
- Diagnostic/
Testing
- Primary
Treatment
- Short Term
Care

**PRIMARY
MILITARY
HOSPITALS**

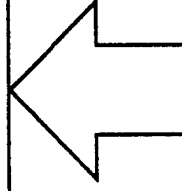
- Advance
Diagnostics
- Specialized
Treatment
- Longer-term
Care

**OUTPATIENT
CLINICS**

- Followup
Evaluations &
Longterm
Care
- On-going
Healthcare

**LIVING/TASK
ENVIRONMENTS**

- On-Going Personal
Monitoring &
Healthcare
- On-going Military
Healthcare



DEVELOPMENT OF SUPPORTING
**ADVANCED MEDICAL TECHNOLOGIES
& FACILITIES**

FORWARD COMBAT CASUALTY CARE



THE PEACE-TIME MILITARY

**FIELD MEDICS
AMBULANCES
HELICOPTERS**

**DEPLOYABLE
HOSPITALS**

**PRIMARY
MILITARY
HOSPITALS**

**OUTPATIENT
CLINICS**

**LIVING/TASK
ENVIRONMENTS**



PSM

- I.D.
- Position
- Vital Signs

MOBILE UNITS

- Diagnosis
- Treatment

MOBILE OUTPATIENT UNITS

- Follow-up Testing/Evaluation
- Diagnosis/Treatment

LSTAT

- Vital Signs
- Basic Life Support

MODULES

- Treatment
- Life Support
- Shortterm Care

ADVANCED MEDICAL TECHNOLOGIES & SYSTEMS

**MEDFAST/
ARMORED
AMBULANCE**

- Life Support
- Treatment

MEDICAL/HEALTHCARE COMPONENTS & SYSTEMS

- Communication
- On-going Personal Health Monitoring
- On-going Military HMO Telemedicine Consultations/Treatment
- Personal Health-maintenance Programs
- Post-Operation Care
- Recovery
- Diagnosis

TELESURGICAL SYSTEMS & OTHER DEVICES

- Treatment Systems
- Diagnosis Systems

REVIEW OF PROJECT ACTIVITIES & RESULTS

This feasibility study has broadly reviewed how different environments can be designed to accomplish the broad health-status monitoring goals noted above and to suggest the directions of development that are most promising. A series of studies have been conducted on (a) different kinds of environments, (b) possibly relevant technologies, and (3) how these technologies could be incorporated into common architectural components. A preliminary design for what an integrated system might look like has been developed. More in-depth studies have been conducted on how embedded sensors might be used to turn several common components into health-status monitoring and reporting devices.

Several preliminary designs were made to assess how common architectural settings and components could be turned into active health-sensing environments. The left part of Figure 4 illustrates the general approach. A telemedicine system is envisioned as linking different habitation and task environments to the several different components of a complex health-care delivery system. The right part of Figure 4 diagrammatically illustrates what a basic system within a habitation environment might actually look like. As noted, the environment itself is not only linked via a telemedicine system to a health-care provider, but the actual environment itself is viewed as an active data acquisition unit.

In the habitation environment shown, there are several settings where health-monitoring via embedded sensors or other technologies could most effectively take place. A prime location for the use of embedded health-sensing technologies in any habitation environment is in bathroom areas that normally accommodate common appurtenances such as lavatories, water closets, showers, mirror/storage chests, etc. It is well understood that individuals in this kind of setting already regularly self-inspect their own bodies (and often do so in an unclothed or partially clothed state). This established behavior could be further reinforced to advantage by the use of embedded health-sensing devices in surrounding bathroom components. Figure 5 suggests just some of the many possibilities -- *as yet not fully explored* -- that exist for health monitoring in this kind of environment. Other spaces within a habitation environment that are also particularly suitable for the use of embedded health-sensing devices include sleeping areas and food preparation areas.

EMBEDDED SENSORS IN HOUSING/TASK ENVIRONMENTS

AUTOMATED HEALTH STATUS MONITORING SYSTEMS

¥ Data Acquisition Systems

¥ Instruction Systems

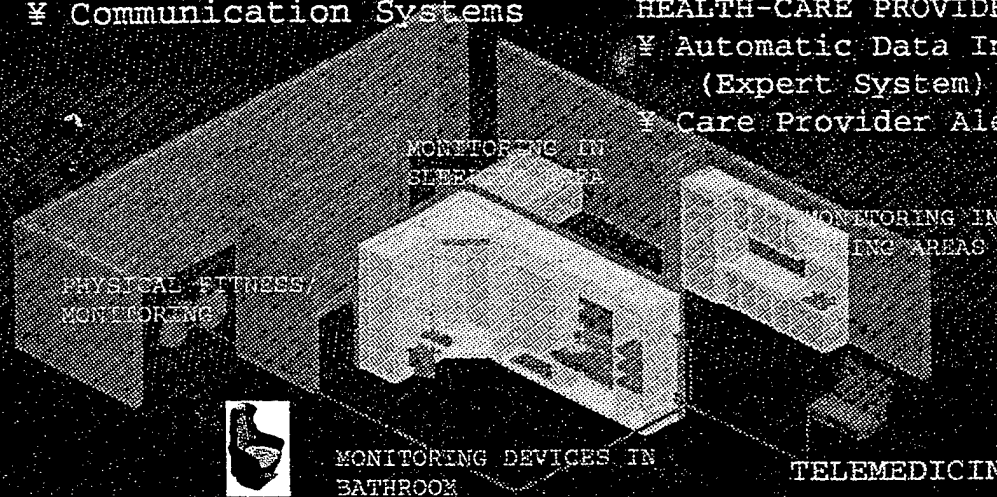
¥ Communication Systems

MILITARY OR CIVILIAN

HEALTH-CARE PROVIDER

¥ Automatic Data Interpretation
(Expert System)

¥ Care Provider Alert System



TELEMEDICINE

COMMUNICATION CENTER

¥ Audio/Visual Input and Output

¥ Teleconferencing with H.M.O.

¥ Health Channel

Schoddek, Harvard - November 1995

EMBEDDED SENSOR TECHNOLOGIES: NON-INVASIVE HEALTH-CARE MONITORING

LIVING UNIT
OR TASK
ENVIRONMENT

Housing or
Task
Environments

Deployable
Modules (Military or
Civilian Applications)

Educational or
Care Facilities

HEALTH-CARE
PROVIDER

TELEMEDICINE
NETWORK

HOSPITALS

OUTPATIENT CLINICS

¥ Standard Clinic

¥ Mobile Clinic

DISTRIBUTED CARE FACILITIES

¥ Telemedicine

¥ Patient Records

¥ Automatic Data Interpretation
and Warning System

SPECIAL TESTING FACILITIES

PHARMACEUTICALS/OTHER

Shipboard (e.g., Submarines)

December 1995

EMBEDDED SENSORS FOR HEALTH-STATUS MONITORING

SKIN CONDITION AND BODY GEOMETRY

- Vision or Laser Scanning System

BIOPHYSICAL SPATIAL MONITORING

- Body Surface Potential Mapping

BREAST EXAMINATION

- Probe or Infrared Device

VOICE UNIT

- Patient I.D.
- Health Instructions

DISPLAY UNIT

- Health Instructions

"HEALTH ARMREST"

- Blood Pressure
- Temperature
- Pulse Oximeter
- Remote Palpitation
- Laser Probe

(electrocardiogram)

EYE EXAMINATION

- Retinal Inspection
- Eye Blood Pressure

RESPIRATORY GAS ANALYSIS/ MONITORING

TEMPERATURE SENSING

AUDITORY TESTING

POSSIBLE MONITORING OPPORTUNITIES & RELATED TECHNOLOGIES (UNDER REVIEW)

FLATULENT GAS ANALYSIS

URINE ANALYSIS

- Biosensors

WEIGHT MEASUREMENT

- Piezoelectric Film

Specific Project Activities and Studies: Focus Groups on Provider Requirements for Health-Sensing Environments

In order to provide insights into what functionality's and capabilities different provider groups would look for in a health-sensing environment, a series of structured focus groups were undertaken. These focus groups were formally structured and administered within a specially equipped room. Using an approach ultimately based on the "Delphi" method, a professional facilitator administered the different sessions. A selected group of care providers were seated in a U-shaped arrangement to facilitate interaction. Each had a terminal in which the participant input responses to the facilitator's questions. Responses were first individually input in a quick-response, brainstorming mode. Group results were then collectively displayed so that each participant could see the other's responses, and the procedure was then iterated until a form of group closure existed. Questions were first broad (e.g., "if you could remotely measure anything in a home environment and see the results at your office, what would you want measured?" Follow-up questions became increasingly specific as broad responses were reviewed.

In the end results were reviewed and a summary document printed out. It should be understood that this approach yields "gut response" suggestions on the part of a series of individual participant individuals that are subsequently formed into consensus rankings (rather than some sort of formal "needs analysis" based on extensive survey data).

While there were few real surprises in these sessions, they did serve to clarify what different provider groups were looking for in a health-sensing environments. They also served to bring into focus certain common needs as well as those that are more diverse, e.g., priority lists of the most useful measures from the point of view of each group were identified as were "clusters" of measurement variables.

The top five primary rank-ordered results from a *direct care physician group* include (1) the need for obtaining blood pressure measurements "on a 24 hour basis -- the number one priority for the group; (2) blood levels, blood sugar, potassium, cholesterol/electrolytes; (3) EKG ECG; (4) medication amounts and use; compliance; (5) real-time visual inspection and communication.

The participants views of "problems," "concerns," and "risks" were also explored. Responses centered around privacy issues, serious liability issues,

and information explosion issues. Liability issues were expressed as a concern particularly since the "tests" were not to be administered in a setting and by personnel controlled by them. The information explosion issue was considered quite serious from several perspectives, including questions of whether collecting data (with possible patient anxiety increases) is worthwhile if there is no treatment response; and patient expectations about care provider use and response to all the data provided. One participant rather jokingly said that he expected the following scenario: "Dear, it is 11:00 p.m. Let's send Dr. ____ five new blood pressure measurements before we go to bed and see what he thinks."

A second group of *home care providers* (e.g., visiting nurses) listed substantially different needs: (1) family/support network information; (2) "condition assessment" (a collective group of vital sign and other condition measures); (3) current and past medical histories; (4) environmental history and setting; and (5) a series of life history, lifestyle, and life management measures.

Specific group outputs are contained in the following reports:
Dorland, John L., *"Focus Groups on Provider Requirements for Health-Sensing Environments: Group #1: Physicians,"* Wellington Technology Integration, Kingston, Ontario, 1996. (Included as Report 96:6-1A, Advanced Health-Care Environments, GSD, Harvard).

Dorland, John L., *"Focus Groups on Provider Requirements for Health-Sensing Environments: Group #1: Home Care Service Providers,"* Wellington Technology Integration, Kingston, Ontario, 1996 (Included as Report 96:6-1B, Advanced Health-Care Environments, GSD, Harvard).

Further less structured interactions occurred with a variety of other clinicians, care providers, etc., with a particular view of understanding "screening" needs.

Specific Project Investigations: Biosensors and Urinalysis, 'Intelligent' Water Closets

In order to explore the feasibility of actually building health-sensing environments, several specific investigations and test developments were undertaken as part of this project. Two typical and ubiquitous building components were ultimately targeted for study (a water closet and a chair).

Prior to attempting to develop actual prototypes, however, it was determined that background studies were needed in two major areas: biosensor technologies and the state of non-invasive urinalysis. These background studies were undertaken as part of a feasibility study on whether or not the common water closet (toilet) could be equipped with biosensors (or other kinds of sensors) to non-invasively obtain valuable health measures from an automated analysis of a patient/users urine specimen. A number of observers have already noted the seemingly great potential for collecting valuable health-care data on a regular basis via the use of an 'intelligent' water closet of this type. News of working prototypes developed by Isao Karube in Japan, for example, attracted considerable attention in recent years.¹ Consequently, it would appear that if such a health-sensing water closet could indeed be developed that it would have great utility in connection with the broader program of 'health-sensing environments' undertaken in this research.

¹ See, for example, Hodgson, John, "First Flush of Success for Diagnosing Diabetes," *New Scientist* 136 (1992).

Survey of Biosensors: In order to understand the design implications of the use of biosensors and related technologies in the development of an 'intelligent water closet' or any other component of a 'health-sensing environment,' a brief survey was undertaken to place the complex and rapidly evolving developments in this field into some perspective. This work is documented in *Project Report 95:9-1B "Survey of Biosensors"* by M. Addington, Advanced Health Care Environments Group, Harvard, Cambridge, MA., 1995.

Briefly, salient findings include the following:

- The entire biosensor field is enjoying almost unprecedented popularity at the moment.
- Biosensors hold great promise for use in non-invasively obtaining a variety of health care information.
- The seemingly almost limited range of chemical selectivity's possible combined with a wide variety of transducer types suggests that a biosensor can be produced to match many needed applications, but the transfer of technology from the research laboratory to practical settings has proceeded very slowly.
- Application initiatives exist in many areas, including clinical chemistry and patient monitoring. Other application domains include bioprocess control, quality control, environmental monitoring, and robotics.
- In the domain of clinical chemistry, significant advances have taken place but technology commercialization remains slow. Single parameter biosensors have been most successful. Robust commercially available products, for example, include sensors which detect glucose and lactate in blood and serum using enzyme electrodes, but biosensors which perform immunoassays have yet to be successfully commercialized. Nonetheless, biosensors have demonstrated the potential to distribute clinical diagnostics away from the centralized laboratory into a variety of other environments, particularly for screening rather than full diagnostic purposes (a good many biosensors are capable of providing semi-quantitative or a yes/no answer for the presence or absence of a particular analyte at a predetermined action level).
- Patient monitoring overlaps with many clinical applications, but key differences lie with sampling technologies. In vivo sensing more fully exploits the potentials offered by biosensors, but problems with biocompatibility, sensor maintenance, and sensor life have severely limited commercialization of any kind of invasive device. For many applications, non-invasive monitoring has thus far been unable to perform with the accuracy and sensitivity of either in vivo or in vivo sampling.
- Primary challenges facing biosensor developers include biocomponent life/stability, biocompatibility, difficulties in collecting multidimensional

information about analytes, sample treatment, and control of interfacial processes.

- Future directions include the development of integrated sensors capable of performing separation, recognition and measurement at its surface, and in single integrated transducers which can incorporate several different biocompounds specific to a number of analytes; the development of biosensors with internal electronic signal processing to create closed-loop receptor-actuator units; artificial prosthesis applications, and scanning microscopy applications.

State of Non-invasive Urinalysis: A brief survey was also undertaken to place the current and future value of urinalysis into perspective. This work is documented in *Project Report 95:12-1A "Non-Invasive Monitoring: Urinalysis"* by M. Addington, Advanced Health Care Environments Group, Harvard, Cambridge, MA.

Briefly, salient findings include the following:

- Urinalysis has long been one of the mainstays of health-screening activities for many years.
- Significant information can, if properly obtained and analyzed, be obtained from urine samples. Microscopy of urine sediment in combination with a test strip pattern are widely used for urinary protein, glucose, blood and pH determinations. Until recently, urine glucose and ketone analyses were the only practical methods for enabling diabetics to routinely assess their glycemic control. Urine screening for drug use has recently risen dramatically. Qualitative methods are steadily being replaced by quantitative methods and there has been a concerted effort separate screening analyses from the more complex diagnostic procedures.
- Despite its successes, urinalysis has come under fire in recent years and may no longer be the procedure of choice. Sampling difficulties are known to pose great problems. Glucosuria (the presence of abnormal amounts of glucose in the urine) has been effectively questioned as a reliable indicator of diabetes. The development of small and accurate blood glucose monitors has rendered urine glucose testing almost obsolete. Confounding chemical plus evasive maneuvers have called into question its usefulness in drug use testing. Although urinalysis is often recommended to assess occult bacteriuria (an indicator of urinary tract disorders), it has been found to have poor predictive value for screening and its use is becoming increasingly restricted. Specimens are easily contaminated resulting in a high prevalence of false positives.

- On the other hand, cytodiagnostic urinalysis (a complete macroscopic and microscopic analysis which combines a physiochemical assessment of urine with a quantitative cytological approach) to the urine sediment examination) has increasingly been effectively used for diagnosing and monitoring renal function.

The 'Intelligent' Water Closet:

The feasibility of developing an 'intelligent' toilet incorporating biosensors (or other sensory technologies) capable of performing some form of urinalysis was reviewed from several perspectives, including: (1) past and on-going experiments (i.e., the Japanese prototype); (2) the current state of interest in the plumbing fixture supply industry; and (3) further interviews with health providers about the potential utility of such devices. In these studies it was assumed that the intent was to not only have an automated and completely non-invasive sensing and analysis capability, but to also have capabilities for automatically transmitting results to relevant and interested care providers.

Prior Prototypes: The prototype developed by RCAST, the Research Center for Advanced Science and Technology at the University of Tokyo under the direction of Isao Karube, and INAX Corporation, a Japanese toilet manufacturer, is the only well-known example of a concerted attempt to develop an intelligent toilet.² In 1992 it was announced that production would begin on toilets that incorporated biosensors for the detection of diabetes. It was noted that eventually the toilet was planned to be incorporated into monitoring systems for health screening. As described by Karube, amperometric detectors determine glucose concentrations from a urine sample collected in a small depression and withdrawn into a chamber. Since their enzyme layer is consumed with each reading, an array of 100 sensors was developed. A new sensor was presented for each test until the array was used up. The array was then discarded and replaced. Research was said to then focused on the design of a multiple analyte sensor which would simultaneously monitor glucose, lactate, uric acid, urea, hemoglobin, antibodies and protein concentration.

Despite the initial fanfare of publicity, it has been extremely hard to identify any subsequent developments of this version of the 'intelligent toilet.' Indeed, there appears to be a retrenchment in any references to the

² See, for example, Karube, I., "Minimally Invasive Diagnostics: Biochemical Sensors," in J.D. Andrade, ed., *Medical and Biological Engineering in the Future of Health Care* (Salt Lake City: University of Utah Press, 1994).

toilet about its prospectus for introduction into the market. There have been numerous innovations in seat design (e.g., user cleaning/sanitation systems, audio masking, and so forth) that have been widely marketed, but these products do not contain any true health-status monitoring capabilities. RCAST itself is unresponsive to inquiries about the toilet. Inquires with various industry groups in this country with close connections to the Japanese toilet industry have only resulted in references back to the original RCAST work.

All indications are that aggressive development of the 'intelligent toilet' in Japan has slowed down considerably (if not virtually stopped) -- a conclusion shared by most knowledgeable observers in the field. Presumably, difficult problems with the inaccuracies of urine analysis with regard to glucose levels coupled with difficulties of sampling and the great potential for sample contamination (particularly from cleansing agents) have reduced interest in continuing active development. Other possible difficulties include doubts about market opportunity (see below).

The Industry: The question of the potential of developing an 'intelligent toilet' was also looked at from the perspective of the plumbing fixture industry -- now dominated by a few large companies. No comparable products were found to already exist.

The plumbing fixture industry in the U.S. is widely regarded by researchers and other innovators in the architectural products field as being one of the more conservative and innovation-resistant components in the entire products industry. Groups that produce the internal mechanics of toilets are generally regarded as more open and forward looking than are actual bowl producers. It has been observed several times that costs of producing bowl molds and changing production runs are so high that bowl producers are extremely resistant to any change. This has been observed even for new water-saving designs that have wide societal and governmental support.

Inquires with consultants knowledgeable about these different segments of the fixture industry indicate that the Japanese experiments are indeed at least somewhat known but skeptically viewed. A perception was found to exist that even if developed that these products were developed that they would find little market response. The clear lack of forward progress of the "Japanese toilet" has not helped perceptions in this regard. In addition, the idea that there might be large new markets opening up for new health-sensing designs is not only viewed skeptically, but (to some) even as a

threat to currently established market products and market bases. Hence, interest in further self-sponsored development has been found to be low.

Since the industry is not inherently receptive to innovations such as an "intelligent toilet", continued strategic thinking is needed concerning how best to get their involvement. It appears that a focus on clarifying incentives and market opportunities is badly needed.

Alternative Technologies: A specific issue that should be clearly addressed prior to further development work is the value or usefulness of alternative technologies that are being rapidly developed which might prove comparable information via other approaches. Blood tests which provide data of a higher value (in the perspective of many) than that which could ever be obtained via an intelligent toilet are becoming more and more minimally-invasive and suitable for use in home or workplace environments. Fully non-invasive diagnostic methods based on methods such as transcutaneous near-infrared spectroscopy and laser polarimetry of the vitreous humor are purportedly capable of yielding great information and are potentially even capable of *continuous* monitoring for many patients via the use of fitted, miniaturized devices (e.g., polarimetry devices consisting of laser/detectors that can be fitted onto a scleral lens; telemetric transmission for relaying data has already been demonstrated in contact lens for monitoring of intraocular pressure). Other approaches have been suggested, albeit all remain in early development stages.

Overall Assessment: The findings above cast many important qualifications and restrictions on the feasibility and usefulness of developing an 'intelligent' water closet.

As noted, urinalysis itself is under fire and is often questioned as being the most effective way of obtaining useful measures and is not the procedure of choice for many. Alternative approaches, albeit typically invasive to a greater or lesser degree, are normally noted as being preferable by many. For renal disorders, urinalysis is still a highly useful approach, albeit the complex sampling and analysis needs associated with cytodagnostic microscopy pose particularly difficult development problems vis-a-vis the idea of an 'intelligent toilet.' Urinalysis is still appropriate for some urinary tract disorders in certain populations. The simple dipstick test still remains attractive for some applications and use conditions -- and in certain military settings may well indeed be highly appropriate. The analysis of urine combined with stools still has seemingly great attraction, particularly in a screening context. Nonetheless, a determination of the specific medical value of the types of information that can be potentially

derived via the use of an intelligent toilet needs to be developed much more clearly than was possible in this initial study. In particular, these determinations must be made *in relation to the use needs of specific groups of medical practitioners or clinicians (in either a military or civilian setting) who might potentially use any information obtained.*

With agreed upon medical objectives, the development of appropriate biosensors for measurement of specific analytes appears possible (biosensor researchers are seemingly invariably optimistic in this regard). The need to have multidimensional sensors is a particular problem, as are needs for stability and maintenance. Biosensor researchers advise, however that development work would undoubtedly be very costly.

Problems associated with the incorporation of biosensors into an actual bowl and obtaining uncontaminated samples (including eliminating the confounding influences of bowl cleansing chemicals) are severe, but not necessarily insurmountable. It is possible to envision various forms of sample acquisition, balancing, and filtering systems that could potentially solve problems in this domain. Nonetheless, the difficulties and costs in doing so should not be underestimated and constitute a major research and development task in their own right.

The issue of obtaining the "involvement" of industry groups involved in plumbing fixture production remains difficult. Certainly, the initial development of a prototype targeted first for "military" applications would help prove to this recalcitrant and resistant industry that the approach is indeed feasible. A role model of success is clearly needed.

In summary, findings to date indicate that some specially targeted forms of intelligent toilet could be extremely valuable. The completely non-invasive character of such a device is a value of extreme importance and would ultimately insure its use over any kind of invasive technique, as long as output medical measures are of comparable reliability and usefulness. At this point in the research and development stage, it appears that it would indeed be possible to develop an intelligent toilet, but development costs would be extremely high. A more realistic immediate approach appears to be to first more fully assess alternative technologies capable of yielding similar health measures before committing to further development of an 'intelligent' toilet. Once the comparative value of different technologies are thoroughly understood, a determination can then be made as to whether it is better to continue for focus on an 'intelligent toilet' or to look to an alternative way of achieving the same ultimate objectives.

Specific Developments: The 'Health Care Chair': A second developmental activity exploring both the utility and technology of how to utilize common architectural components in connection with health-sensing environments has been focused on the 'health-care chair.'

Research Objectives: The 'health-care chair' is intended for use in any of the target environments previously discussed -- the workplace, housing, outpatient clinics, etc. It is conceived of as a multipurpose chair for monitoring different measures important to the evaluation of a user's health and well-being via the use of embedded devices. In addition to different health monitoring devices, the design is envisioned as incorporating different information display, instruction, and communication systems -- both audio and visual -- that are generally part of a total care package.

Different versions of the chair are conceived for different uses. Chair designs can be tailored for preventive care, post-operative recovery care, certain treatments, or long-term care. In the military context, versions of the chair could be used for follow-up post-operative care in forward mobile hospitals. Other versions could be used for screening and evaluation in remote locations. Clinical versions could be used in a military hospital to assist in normal checkups and screening. Special versions could be used in the peace-time to aid military personnel with specific problems, e.g., asthma.

The health-care chair is conceived of as an integral component of a larger health-sensing environment. The chair itself is envisioned as being composed of modular and interchangeable subcomponents. Different components would be designed in response to the different intended use needs noted above. A basic chair structure would be designed to receive these interchangeable components.

Development of First Prototype: In order to explore further the concept of a 'health-care chair', a simple prototype was constructed and evaluated. This work is documented in detail in the following report: Schodek, Daniel, "The Health-Care Chair," Report 96:6-1A: *Advanced Health-care Environments*, Harvard, Cambridge, MA., 1996.

The following briefly summarizes the work done to date. The first model (Prototype 95.A-1) is illustrated in Figure 6. Intended basic systems and functionality's include:

INFORMATION, INSTRUCTION & TELEMEDICINE CONSULTING SYSTEMS

- An interactive media system (sound, visual)
- An interactive communication system
 - Care providers
 - Pharmacists
 - Family/friends support groups
 - Appointment scheduling
 - Other
- An information system (on-line access to medical information)
- Personalized health-care data systems
- Personalized health-care instruction systems
 - How to use chair
 - Tailored programs for personal care needs
 - Prompts for specific actions (medicine intake, exercise, etc.)

DIAGNOSTIC SYSTEMS

- Basic monitoring capabilities
 - Blood pressure
 - Temperature
 - Pulse rate
 - Weight
 - Many other capabilities can be envisioned (under development - e.g., glucose, blood oxygen, etc.)
- Modules for specific conditions (e.g., asthma, cardiovascular, etc.) (under development)

RECOVERY AND SPECIALIZED TREATMENT (Under Development)

Other intended functionality's include:

- Microclimate control (heating/cooling/lighting)
- Air quality evaluation and control

Issue areas to be addressed include:

- Bacteria growth in chair materials
- Ergonomic issues
- Special problems (e.g., pressure sores)

The first prototype is not fully functional,. Only a few sensors are currently configured to send their output signals into a computer environment and ultimately tied into the more extensive information and communication system envisioned. Nonetheless even chair in its current state serves to illustrate the potential of this approach. It has been

demonstrated to a number of groups and always generates interest, including numerous suggestions of "can you make it do...".

Experience with the first prototype suggests that a significant amount of research and development work needs to be done to further explore the concept. Major needs include:

- (1) Additional definition of target patient/user groups and their health-care providers in relation to the use of the chair in specific settings and for specific purposes.
- (2) Further definition of exact monitoring and data communication needs for targeted applications.
- (3) Identification of relevant medical device technologies -- with a particular view towards how individual devices can be reconfigured and integrated with other devices within the highly constrained chair environment.
- (4) Development of system integration strategies and devices.
- (5) Development of physical integration strategies and approaches (e.g., chair arms with interchangeable 'modular' components).
- (6) Attention to ergonomic and other human factor considerations.

Future Work: In the next project phase, different combinations of devices will be identified to respond to varying needs. A modular design approach is envisioned so that different chair versions can be built off of the same basic structure. A primary focus will be on integrating the various systems. A second prototype suitable for demonstration purposes will be built in the next stage.

D.SCHODEK
Harvard, 95/96
DARPA

HEALTHCARE CHAIR

BASIC SYSTEMS PROTOTYPE 95-A.1

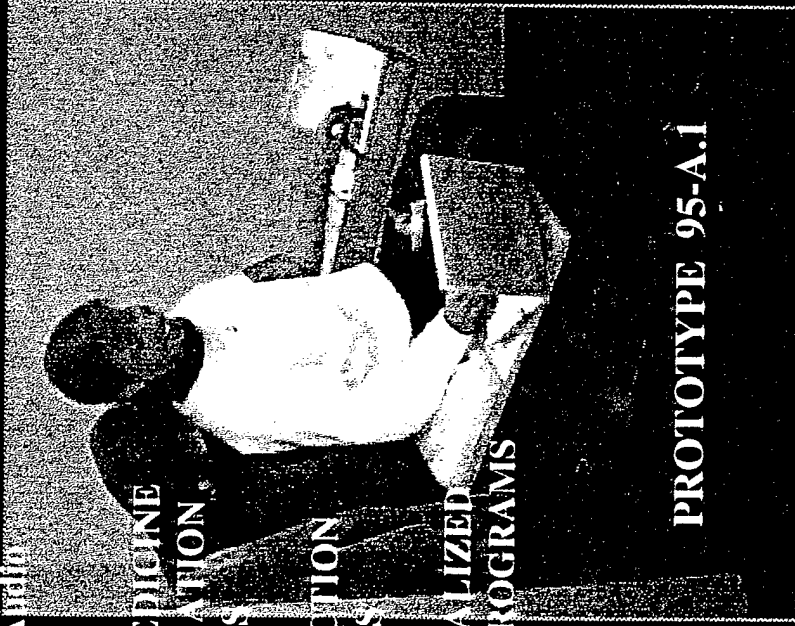
INTERACTIVE MEDIA SYSTEM

- Sound/Audio
- Visual

TELEMEDICINE INFORMATION SYSTEMS

INSTRUCTION SYSTEMS

PERSONALIZED CARE PROGRAMS



PROTOTYPE 95-A.1

MODULAR DESIGN APPROACH

- Interchangeable Subcomponents
- Modular Subcomponents for Preventive, Recovery, Longterm Care Chairs

BASIC MONITORING CAPABILITIES

- Blood Pressure
- Pulse Rate
- Temperature
- Weight
- Other

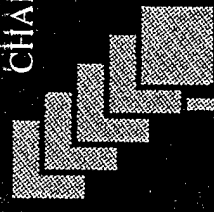
SPECIALIZED MONITORING MODULES

- Asthmatic
- Diabetic
- Cardiovascular
- Other

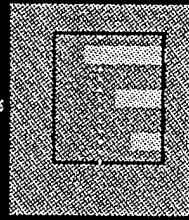
RECOVERY MODULES

- Post-Operative
- Medicine Compliance
- Other

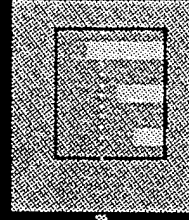
EMBEDDED SENSORS IN
CHAIR



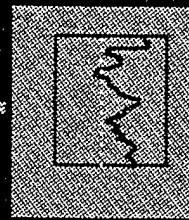
CHAIR DISPLAY:
PERSONAL FILE



CARE SUPPORT FOCUS:
FAMILY/FRIENDS



PRIMARY CARE
PROVIDER



SPECIALIST/OTHER

